

Dockets Management Branch
The Food and Drug Administration
Department of Health and Human Services, Rm. 1-23
12420 Parklawn Drive
Rockville, MD 20857

7114 '99 SEP 10 P1:53

Re: 99P-1340/CP 1
Petition to Have "Eternity eau de parfum" Misbranded

Overview

I am expressing my whole-hearted support for the petition submitted in May of this year by the Environmental Health Network (EHN) to have Calvin Klein's "Eternity eau de parfum" declared misbranded, based on FDA regulations 21CFR Sec. 740.1, 21CFR Sec. 740.2, and 21CFR Sec. 740.10.

My support for this petition is specifically based on the portion of regulation 21CFR Sec. 740.10, which states:

"Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel: 'Warning—The safety of this product has not been determined.'"

The EHN petition shows that "Eternity" contains toxic ingredients, and ingredients whose safety has not been substantiated, and also that its packaging does not contain the requisite warning label.

I personally am not chemically sensitive, but have loved ones who are. When they are exposed to "Eternity" or other fragrances, they experience debilitating effects, such as pain in their nostrils and sinuses, immediate headache, sudden fatigue, a steep decline in mental functioning (including short term memory and the ability to process information and express themselves clearly), and — in some cases, but not all — seizures.

Conclusion

Not properly labeling products that contain known toxic ingredients is a serious public health issue. Although some people do not currently react to the toxic ingredients in products like "Eternity", the FDA (not to mention the EPA) knows that these ingredients *are* dangerous. And when it comes to perfume, no one knows how much is "too much". At the very least, the public has a right to know what is in the products they purchase, and the manufacturers of those products have a duty to provide that information. I ask that your office follow its own mandate and, in that regard, carefully consider the EHN petition to misbrand "Eternity" and thereby help protect us all.

Sincerely,

99P-1340

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Docket's Management Branch
The Food and Drug Administration
Department of Health & Human Services, Rm. 1-23
12420 Parklawn Dr.
Rockville, MD 20857

Date: 9-3-99

Re: **99P-1340/CP 1** — Petition to Have *Eternity eau de parfum* declared "Misbranded"

Dear Sir or Madam:

In May 1999, the Environmental Health Network (EHN) submitted the above petition to have Calvin Klein's *Eternity* eau de parfum declared "misbranded." I am writing because I fully support this petition and request that the FDA give it careful attention with regard to your regulations 21CFR Sec. 740.1, 21CFR Sec. 740.2, and 21CFR Sec. 740.10. Regulation 21CFR Sec. 740.10 states:

Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel:

"Warning — The safety of this product has not been determined."

As the petition shows, *Eternity* contains toxic ingredients and ingredients whose safety have not been substantiated. There is no warning label on its packaging.

We all have a right to know the status of safety testing of the ingredients in products such as *Eternity* so that we can protect ourselves and our families from toxic chemicals that may cause health problems. Most people are not aware that most fragrance materials have only limited safety testing. They wrongfully assume these products are safe to use in any setting and are surprised when people complain.

Like tobacco smoke, the harmful chemicals currently used in these products may affect the health of many people, including: people with asthma, chemical sensitivities, chronic fatigue, and other environmental illnesses. Children are particularly vulnerable to toxic chemicals found in products purchased and used by their parents, caregivers and teachers. When I am exposed to **fragrance products** I can experience any of the following symptoms based upon the chemical fragrance product I encounter:

- | | | | |
|---|---|---|--|
| <input type="checkbox"/> anaphylaxis/shock | <input type="checkbox"/> double vision | <input type="checkbox"/> incoherence | <input type="checkbox"/> nausea |
| <input type="checkbox"/> anxiety, restlessness | <input type="checkbox"/> ear pain | <input type="checkbox"/> incontinence | <input type="checkbox"/> nose bleeds |
| <input type="checkbox"/> asthma | <input type="checkbox"/> eczema | <input type="checkbox"/> irritability | <input type="checkbox"/> rashes |
| <input type="checkbox"/> breathing difficulty | <input type="checkbox"/> eyes, watery or dry | <input type="checkbox"/> joint aches | <input type="checkbox"/> seizures |
| <input type="checkbox"/> bronchitis | * <input checked="" type="checkbox"/> fatigue | <input type="checkbox"/> laryngitis | <input checked="" type="checkbox"/> short-term mem. loss |
| <input type="checkbox"/> can't concentrate | <input type="checkbox"/> flushing | <input type="checkbox"/> lethargy | <input type="checkbox"/> sinusitis |
| <input type="checkbox"/> coughing | <input checked="" type="checkbox"/> headaches | <input type="checkbox"/> lymph nodes swell | <input type="checkbox"/> sneezing |
| <input type="checkbox"/> depression | <input checked="" type="checkbox"/> heart beat irregularity | <input type="checkbox"/> mood swings | <input type="checkbox"/> sores, skin/mouth |
| <input type="checkbox"/> disorientation | <input type="checkbox"/> hives | <input type="checkbox"/> muscle pain/weakness | <input type="checkbox"/> swallowing difficulty |
| <input type="checkbox"/> dizziness | <input type="checkbox"/> hypertension | <input type="checkbox"/> nasal congestion | <input type="checkbox"/> tinnitus |
| <input type="checkbox"/> other: <u>Inability to sleep, and light, disturbed sleep</u> | | | |

Please act on behalf of the millions of people who have suffered physical illness and injury resulting from fragrance exposure at work, at school and in social settings. These toxic chemicals act as powerful barriers to people disabled by asthma and chemical sensitivities. Toxic chemicals in fragrances have already ruined countless lives. Thank you.

Sincerely,

Sharon VanduBoon
your name

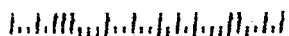
7914 Threemile Rd. NE Grand Rapids, MI 49525
address; city/st/zip

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Attn: 99P-1340/CP 1

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